

REMARKS/ARGUMENTS

Claims 1-21 and 24-25 were pending at the time of the mailing of the outstanding Office Action. By this amendment, claims 2 and 8 have been cancelled without prejudice or disclaimer as to the subject matter contained therein. Claims 1, 3, 9, 11, 13, 18 and 20 have been amended. Claim 13 has been amended to independent form. No new claims have been added.

In the Office Action of 16 October 2008, the Examiner objected the specification for failure to include all of the section headings provided in 37 C.F.R. 1.77(b). The specification has been amended accordingly. The Examiner also objected to claim 2 as being of improper dependent form. Claims 1-2, 24 and 25 were rejected under 35 U.S.C. § 102(e) as anticipated by Elliot (U.S. Pat. Pub. No. 2003/0236567, hereinafter "Elliot"). Claims 1-3 were rejected under 35 U.S.C. § 102(e) as anticipated by Wironen (U.S. Pat. No. 6,685,626, hereinafter "Wironen"). Under 35 U.S.C. § 103(a), the Examiner rejected claims 4-7 as being unpatentable over Wironen and claims 3-7 as being unpatentable over Elliot. Claims 8-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Elliot in view of Pastorello et al. (U.S. Pat. No. 6,642,213, hereinafter "Pastorello") and Collombel et al. (U.S. Pat. No. 5,166,187, hereinafter "Collombel"). Claims 8-20 also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Wironen in view of Pastorello and Collombel. Claim 21 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Elliot in view of Swan et al. (U.S. Pat. No. 5,563,056, hereinafter "Swan"). Claim 21 was also rejected under 35 U.S.C. § 103(a) as being unpatentable over Wironen in view of Swan.

Claim 1 has been amended to recite that the chitosan is present at least in partial areas or partial layers, as previously recited in claim 2, which has now been cancelled. The previous objection to claim 2 is now believed to be moot.

Claim 1 has also been amended to recite that the polysaccharide layer has a composition such that the in vivo degradation of the polysaccharide layer is slowed from the outside in the direction of the main body of the implant, as previously recited by claim 8. Therefore, the previous rejections of claims 1-7 as being anticipated by or obvious in view of Elliot or Wironen are believed to be moot.

Claims 8-20 were rejected as being obvious over Elliot in view of Pastorello and Collombel. To establish a prima facie case of obviousness, three requirements must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. There must also be a reasonable expectation of success and the prior art reference or references must teach or suggest all of the claim limitations. (MPEP § 2143.)

In the Office Action, it was maintained that Elliot teaches an implantable prosthesis which can be composed of hyaluronic acid and chitosan but does not teach the rate of degradation of the polysaccharide layer. It was further maintained that Pastorello teaches that the degradation time of an implant containing a hyaluronic acid derivative can be adjusted by amount of esterification of the hyaluronic acid. It was additionally maintained that Collombel provides the usage of chitosan in a biomaterial application and that the rate of degradation can be adjusted according to the molecular weight and degree of acetylation. However, even in combination, these references do not teach or suggest all the limitations of amended claim 1, nor is there any teaching or suggestion to combine these references.

Neither Pastorello nor Collombel teaches or suggests a polysaccharide layer which is a combination of chitosan and hyaluronic acid. Additionally, neither of these references teach or suggest the use of hyaluronic acid or its derivatives (in the case of Pastorello) or chitosan (in the case of Collombel) as a coating for an implant. Instead, Pastorello provides "a three-dimensional prosthesis...containing a hyaluronic acid derivative." (See abstract.) The prosthesis is described as comprising "a three-dimensional matrix having an essentially fibrous or porous structure." (Abstract.) Such a three-dimensional prosthesis may be used to reconstruct body parts. (Abstract.) However, no teaching or suggestion is indicated that the hyaluronic acid-containing compound may be used as a coating for an implant. In fact, the teaching of Pastorello that the composition has "an essentially fibrous or porous structure" would tend to teach away from use of a hyaluronic acid derivative with an adjustable degradation rate as a coating as recited in claim 1.

Likewise, Collombel also does not teach or suggest a coating for an implant. Collombel does not teach or suggest the use of the chitosan-containing composition in any association with an implant, much less as an implant coating, but merely provides for its use as an artificial

skin. No teaching or suggestion of adjusting the degradation rate of a chitosan compound as a coating on an implant is observed. Therefore, neither Pasterello nor Collombel teach or suggest the use of a combination of chitosan and either hyaluronic acid or a hyaluronic acid derivative as a coating for an implant where the degradation rate of the coating can be adjusted.

Claim 13 has been amended to independent form. While the Office Action indicated that claim 13 was rendered obvious by the combined teachings of Elliot, Pasterello and Collombel, no explanation was provided as to which of these references provided the teaching or suggestion of a polysaccharide layer that comprises at least two partial layers having different degradation behaviors, where the degradation behavior within each partial layer continuously changes or is constant throughout the partial layer. The Applicants maintain that none of the cited references teach or suggest these limitations.

Therefore, the Applicants maintain that independent claims 1 and 13 patentably distinguish over Elliot, Pasterello and Collombel, either individually or in combination. Likewise, claims 3-7, 9-12, 14-21 and 24-25, which depend from and include all the limitations of either claim 1 or claim 13, also patentably distinguish over Elliot, Pasterello and/or Collombel. Withdrawal of the rejection of claims 8-20 under 35 U.S.C. § 103(a) as unpatentable over Elliot in view of Pasterello and Collombel is requested.

Similarly, claims 8-20 were rejected as being obvious over Wironen in view of Pastorello and Collombel. In the Office Action, it was maintained that Wironen teaches a biocompatible coating for a metallic implant, where the coating may include hyaluronic acid and chitosan. However, it was also conceded that Wironen does not teach the rate of degradation of the polysaccharide layer. It was further maintained that Pastorello teaches that the degradation time of an implant containing a hyaluronic acid derivative can be adjusted by amount of esterification of the hyaluronic acid and that Collombel provides the usage of chitosan in a biomaterial application and that the rate of degradation can be adjusted according to the molecular weight and degree of acetylation. Distinctions between Pastorello and the present invention and between Collombel and the present invention are provided above and are repeated with regard to this rejection.

Wironen provides a coating for a metallic implant that includes hyaluronic acid and chitosan only for a limited purpose – the creation of adhesions between implants and anatomical structures to stabilize implants. One of ordinary skill in the art would not have

found any suggestion or motivation to combine the adjustable biodegradation properties of a compound containing either hyaluronic acid or chitosan (neither of which is disclosed as suitable for use as a coating) with an adhesion-promoting composition of Wironen to arrive at the present invention as recited in amended claim 1.

As provided above, claim 13 has been amended to independent form. While the Office Action indicated that claim 13 was rendered obvious by the combined teachings of Wironen, Pasterello and Collombel, no explanation was provided as to which of these references provided the teaching or suggestion of a polysaccharide layer that comprises at least two partial layers having different degradation behaviors, where the degradation behavior within each partial layer continuously changes or is constant throughout the partial layer. The Applicants maintain that none of the cited references teach or suggest these limitations.

Therefore, the Applicants also maintain that independent claims 1 and 13 patentably distinguish over Wironen, Pasterello and Collombel, either individually or in combination. Likewise, claims 3-7, 9-12, 14-21 and 24-25, which depend from and include all the limitations of either claim 1 or claim 13, also patentably distinguish over Wironen, Pasterello and/or Collombel. Withdrawal of the rejection of claims 8-20 under 35 U.S.C. § 103(a) as unpatentable over Wironen in view of Pasterello and Collombel is requested.

Finally, claims 21 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Elliot in view of Swan et al. and as being unpatentable over Wironen in view of Swan. In the Office Action, it was stated that Elliot and Wironen each teach the invention recited in claim 1. Swan was relied upon for the teaching immobilizing a chemical specie in a three-dimensional crosslinked matrix by bringing a desired chemical specie and a polymeric coupling compound together in covalent bonding proximity. In light of the amendments made to claim 1, the Applicants respectfully maintain that neither Elliot nor Wironen teach the invention of claim 1. Therefore, none of Elliot, Wironen and Swan teach or suggest all the limitations of claim 21. Withdrawal of the rejections of claim 21 as obvious over Elliot or Wironen in view of Swan is respectfully requested.

The outstanding Office action was mailed on 16 October 2008. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. Therefore, no extension of time or accompanying fee is believed to be due in making this response. Nevertheless, the

Applicants hereby make a conditional petition for an extension of time for response in the event that such a petition is required. In this response, claims 2 and 8 have been cancelled and claim 13 has been amended to independent form. No claims have been added. As a result, 21 claims, 2 of which are independent claims, are currently pending. Therefore, no additional fees are believed to be due, as the Applicants previously paid for 3 claims in excess of 20. However, in the event that a fee for the filing of his response is insufficient, the Commissioner is authorized to charge any fee deficiency or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

/John J. Cunniff/

John J. Cunniff
Reg. No 42,451
Hahn Loeser + Parks LLP
One GOJO Plaza
Suite 300
Akron, OH 44311

Attorney for Applicants